K101722

APR - 1 2011

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

Sponsor: Bard Medical Division
C.R. Bard, Inc.
8195 Industrial Blvd.
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Date of Submission: March 31, 2011

Proprietary Name: ALYTE™ Y-Mesh Graft

Common Name: Surgical Mesh

Regulation: 21 CFR 878.3300

Regulatory Class: II

Product Codes: OTO – Mesh, Surgical, Gynocological, For Apical Vaginal Prolapse, Transabdominally Placed

Predicate Device(s): ALYTE™ Y-Mesh Graft (BARD Graft), CR BARD, K090739
Caldera Mesh, Caldera Medical, K060004
AMS Sacral Colpopexy Sling, American Medical Systems, K010931

Device Description: The ALYTE™ Y-Mesh Graft is composed of lightweight/ultralightweight, non-absorbable, monofilament, polypropylene mesh. The Y configuration of the design provides two wide layers of mesh (A/P flaps) for anterior and posterior vaginal attachment that combine seamlessly into one double layer mesh (Sacral flap) for attachment to the anterior longitudinal ligament. The ALYTE™ Y-Mesh Graft contains a center line indicator created by knitting a blue polypropylene fiber in the mesh. The anterior and posterior flaps (A/P flaps) contain additional lateral indicator stripes also made from the same blue polypropylene fiber to provide guidance for placement. The graft is designed such that the surgeon will be able to alter/trim the graft to different sizes and lengths as required to fit each patient's anatomical requirements without unraveling.

Indications for Use: The ALYTE Y-Mesh Graft is indicated for use as a bridging material for sacrocolposuspension / sacrocolpopexy (laparotomy or laparoscopic approach) where surgical treatment for vaginal vault prolapsed is warranted.

Technological Characteristics Summary: The ALYTE™ Y-Mesh Graft is composed of a non-absorbable, polymeric mesh material which is the same technology used in each of the selected predicates. The design of the subject device is a Y configuration, which is identical to the predicate Alyte Y-Mesh (K090739) and similar to the AMS Sacral Colpopexy Sling (K010931).

Non Clinical Testing: Non-clinical performance of the subject device was characterized in accordance with FDA *Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh* (March 22, 1999) to demonstrate substantial equivalence to the predicate device for the intended use of sacrocolposuspension. The components of the subject device have been subjected to mechanical testing and are identical to the predicate Alyte Y-Mesh (K090739) and substantially equivalent to the Caldera Mesh device (K060004). The subject device is unchanged from the device cleared in K090739; therefore stability and biocompatibility testing was not repeated.

Clinical Testing: Data were provided from a 2010 European retrospective survey of 17 surgeons who reported outcomes following 69 sacrocolpopexy procedures (approximately 2/3 laparoscopic, 1/3 laparotomy) in women with POP-Q stage >/= Stage 2 using the Alyte Y-mesh graft. Median POP-Q stage at median follow-up of approximately 6 months was Stage 0-1. Rate of erosion of mesh in this survey was 2/69 (2.9%). The 510(k) was also supported by a review of clinical studies described in the peer-review medical literature comparing different graft materials used in the pelvic floor space. Six of the studies evaluated synthetic mesh for sacrocolpopexy. Although different graft materials were compared, all studies showed effectiveness of synthetic mesh in sacrocolpopexy to correct pelvic organ prolapse. Vaginal erosion was within a clinically acceptable range.

Conclusions: The data provided in this submission demonstrate that the Alyte Y-Mesh Graft is substantially equivalent to the predicate devices for the proposed indications for use, i.e for use as a bridging material for sacrocolposuspension/sacrocolpopexy (laparotomy or laparoscopic approach) where surgical treatment for vaginal vault prolapse is warranted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

APR 1 2011

Mr. Scott Robirds
Vice President, Regulatory and Clinical Affairs
Bard Medical Division
C.R. Bard, Inc.
8195 Industrial Blvd.
COVINGTON GA 30014

Re: K101722
Trade/Device Name: Alyte™ Y-Mesh Graft
Regulation Number: 21 CFR §878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: OTO
Dated: January 26, 2011
Received: January 27, 2011

Dear Mr. Robirds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K101722

Device Name: ALYTE™ Y-Mesh Graft

Indications for Use:

The ALYTE™ Y-Mesh Graft is indicated for use as a bridging material for sacrocolposuspension / sacrocolpopexy (laparotomy or laparoscopic approach) where surgical treatment for vaginal vault prolapse is warranted.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K101722